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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,329	10/28/2003	David Schneider	SDR-10802/01	4848

25006 7590 01/27/2006

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EXAMINER

DRYDEN, MATTHEW DUTTON

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/695,329	<b>Applicant(s)</b> SCHNEIDER, DAVID	
	<b>Examiner</b> Matthew D. Dryden	<b>Art Unit</b> 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/28/2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/17/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification***

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

### ***Claim Objections***

Claims 15-22 are objected to because of the following informalities: the claims recite "the kit of claim 11" and there is no kit mentioned in claim 11. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 6, 9 –14, 18, 19, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thieme et al (5871905) in view of Doneen et al (6102872).

Thieme et al discloses the claimed invention except for the saliva collection device having a salivation catalyst. Thieme et al discloses a saliva collection device, a collection device, and a storage solution containing a preservative (see Column 11, lines 39-45). Thieme et al also disclose a preservative that includes a fungicide and a bactericide (see Column , lines 28-48). Doneen et al teaches a saliva-sampling device that includes a salivation stimulant that includes a citric acid that is found in both lemons and oranges (Columns 5-6, 35-10), to make sure a sufficient amount of saliva is available for collection and analysis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Thieme et al with a salivation catalyst, as taught by Doneen et al, to make sure a sufficient amount of saliva is available for collection and analysis.

Regarding claims 11-14, Thieme et al discloses the claimed method steps except for the salivation catalyst, the rejection of which is discussed above using the patent to Doneen et al, for the method steps see Columns 7-9, lines 24-48 (Specifically Column 8, lines 10-40), for collection and assaying see Columns 11-12 lines 39-41.

Claims 2, 3, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thieme et al in view of Doneen et al as applied to claim 1 above, and further in view of Goldstein et al (5335673). Thieme et al discloses the claimed invention

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except for the container comprising a resealable tube and the tube being a polyethylene vial. Goldstein et al discloses an oral collection device and method for immunoassay that includes a resealable tube that is made out of polyethylene (Column 7, lines 22-44). The purpose of providing such a tube is to allow for the tube or vial to be opened and closed a multitude of times and to protect against contamination. It would have been obvious to one having ordinary skill in the art at the time the current invention was made to further modify the device of Thieme et al with a polyethylene resealable tube, as taught by Goldstein et al, to allow for the tube or vial to be opened and closed a multitude of times and to protect against contamination.

Claims 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thieme et al in view of Doneen et al as applied to claim 1 above, and further in view of D'Angelo (5910122). Thieme et al as modified discloses the claimed invention except for the saliva collection device comprising a transfer pipette having a compression end and an intake end. D'Angelo discloses a saliva collector with an aspirating pipette (see Abstract), to facilitate for the collection of a greater volume of saliva. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device Thieme et al with a transfer pipette, as taught by D'Angelo, to facilitate for the collection of a greater volume of saliva.

Claims 7, 8, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thieme et al in view of Doneen et al as applied to claim 1 above, and further in view of Putcha et al (6133036). Thieme et al as modified discloses the claimed invention except for the specific solution disclosed in claim 7, comprising: sodium

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chloride,  $\text{NaHPO}_4$  and  $\text{NaH}_2\text{PO}_4$  in an aqueous concentration to provide a 50mM phosphate solution and .5-2.0 g sodium benzoate. However, the applicant provides two other preservative solutions that can also be used in the same application and device. Therefore the solution is deemed not to be a critical component of the current application and at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a preservative solution of sodium chloride,  $\text{NaHPO}_4$  and  $\text{NaH}_2\text{PO}_4$  in an aqueous concentration to provide a 50mM phosphate solution and .5-2.0 g sodium benzoate. Applicant has not disclosed the specifics of the solution providing an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Putcha et al's preservative solution, and applicant's invention, to perform equally well with either the solution taught by Putcha et al or the claimed solution because both solutions would perform the same function of preserving the collected sample equally well. Therefore, it would have been prima facie obvious to further modify Putcha et al to obtain the invention as specified in claims 7 and 8 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Putcha et al.

#### ***Prior Art***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 5,114,863 McCombs et al discloses an immunosorbent assay for alpha-1-antitrypsin, kit employing said assay monoclonal antibody to alpha-1-antibody and hybridoma for producing said monoclonal antibody

U.S. Pat. No. 5,260,031 Seymour discloses a saliva sampling device with sample adequacy indicating system

U.S. Pat. No. 5,981,293 Charlton discloses a fluid collection kit and method

U.S. Pat. No. 6,152,887 Blume discloses a method and test kit for oral sampling and diagnosis

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MDD



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